IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

MDL No. 2409

Civil Action No. 1:12-md-02409

This Document Relates To: ALL ACTIONS

PLAINTIFFS' BENCH MEMORANDUM REGARDING TEVA'S WAIVER OF ATTORNEY-CLIENT PRIVILEGE AS TO CERTAIN SPREADSHEETS

BACKGROUND

Plaintiffs seek production of approximately 163 improperly withheld Teva spreadsheets forecasting the launch or market entry of Esomeprazole. During discovery in this matter, Defendant Teva withheld approximately 163 spreadsheets created, emailed, or received by Jennifer King, Director of New Products for Teva Pharmaceuticals, on the basis of attorney-client privilege. Now, at trial, Teva's in-house counsel, Staci Julie, has testified on the very subject matter of these spreadsheets that they previously blocked from discovery. The law is clear that such use of the attorney-client privilege as a sword and a shield is not permissible.

The 163 spreadsheets at issue are variously described as "Spreadsheet[s] to counsel for the provision of legal advice regarding the launch or market entry for Esomeprazole," "Spreadsheet[s] to counsel containing information prepared at the request of counsel regarding the launch or market entry for Esomeprazole," "Spreadsheet[s] to counsel providing information

¹ See Teva Privilege Log, dated June 10, 2013 (Exhibit 1), entries 578-646; 1036-1120; Teva Privilege Log, dated September 10, 2013 (Exhibit 2), entries 1237, 1243, 1377-79, 2547, 2549, 2551, 2925, 2938, 2943; Oct. 29, 2014 Tr., Vo. 2 (Exhibit 3), 84:3-7; see also June 4, 2013, letter from K. Walker to J. Opper (Exhibit 4) (in which Teva states it does not intend to rely on an advice of counsel defense).

for the provision of legal advice regarding Nexium litigation or settlement," "Spreadsheet[s] to counsel containing information prepared at the request of counsel regarding ongoing litigation, including Nexium and Prilosec litigation," "Spreadsheet[s] to counsel prepared at the request of counsel for the provision of legal advice regarding the Esomeprazole ANDA or regulatory approval," and "Spreadsheet[s] reflecting legal advice regarding the launch or market entry for Esomeprazole." Despite withholding these documents on the basis of attorney-client privilege and the work-product doctrine, Teva's counsel elicited testimony from Staci Julie, Teva's inhouse counsel, in which Ms. Julie provided her own made-to-order spreadsheets about the same subject matter that Teva apparently believes is helpful to its case.

Teva should be ordered to immediately produce all of the King spreadsheets identified on its privilege log so that Teva's witnesses, including Ms. King, can be examined regarding those materials, and so that Plaintiffs can (as best they can at this late date) test Defendants' assertions and defenses, or any other appropriate relief.

ARGUMENT

A. Ms. Julie Waived the Privilege

A party may not use the attorney-client privilege as both a sword and a shield by selectively introducing testimony or other evidence that supports its litigation position while refusing to let the jury test the accuracy of that testimony by invoking the attorney-client privilege.³ This principle is well established. As the Supreme Court noted in *Mitchell v. United States*:

² See Exhibit 1, entries 578-646; 1036-1120; Exhibit 2, entries 1237, 1243, 1377-79, 2547, 2549, 2551, 2925, 2938, 2943.

³ In re PolyMedica Corp. Securities Litig., 235 F.R.D. 28, 32 (D. Mass. 2006) (Young, J) ("A party cannot put attorney-client communications at issue by raising [a] defense and then assert the privilege to shield any unfavorable evidence.").

It is well established that a witness, in a single proceeding, may not testify voluntarily about a subject and then invoke the privilege against self-incrimination when questioned about the details. . . .

The justifications for the rule of waiver in the testimonial context are evident: A witness may not pick and choose what aspects of a particular subject to discuss without casting doubt on the trustworthiness of the statements and diminishing the integrity of the factual inquiry. As noted in *Rogers* [v. United States, 340 U.S. 367, 371 (1951)], a contrary rule "would open the way to distortion of facts by permitting a witness to select any stopping place in the testimony."

Here, Teva asserted the privilege as to 163 spreadsheets relating to esomeprazole created, received, or sent by Teva's executive in charge of forecasting. These spreadsheets contain, among other things, Teva's assessment of the value to Teva of entering the generic esomeprazole market. For example, privilege log entries 1036-1057 are "spreadsheets reflecting legal advice regarding the launch or market entry for Esomeprazole" dated between March 7, 2006, and May 8, 2006, shortly after Teva's ANDA was filed and around the time of the filing of the *AstraZeneca v. Teva* Nexium patent litigation. Likewise, certain privilege log entries⁵ are "spreadsheet[s] reflecting legal advice and analysis regarding the launch or market entry for esomeprazole" dated between May 6 and June 9, 2009, during which time Teva and AstraZeneca were in the midst of Nexium and Prilosec settlement negotiations; privilege log entry 646 is a "spreadsheet to counsel prepared at the request of counsel for the provision of legal advice regarding the Esomeprazole ANDA or regulatory approval" dated August 26, 2009 (the same date that Teva received the first drafts of the Nexium and Prilosec settlement agreements); privilege log entries 1099 and 1100 are "spreadsheets reflecting legal advice regarding the

⁴ 526 U.S. 314, 321-22 (1999); *See also U.S. v. Parcels of Land*, 903 F.2d 36, 43 (1st Cir. 1990) (affirming district court's decision to strike defendants' affidavit on summary judgment after he had previously refused to answer deposition questions claiming privilege); *Serafino v. Hasbro, Inc.*, 82 F.3d 515, 518 (1st Cir. 1996) ("We think that in the civil context, where, systemically, the parties are on a somewhat equal footing, one party's assertion of his constitutional right should not obliterate another party's right to a fair proceeding").

launch or market entry for Esomeprazole" dated January 6, 2010 (the date of the AstraZeneca / Teva settlements); and 1101-1110 are "spreadsheets reflecting legal advice regarding the launch or market entry for Esomeprazole" (dated during the interim period in which drafts were exchanged and negotiations were conducted).

Despite previously withholding discovery on the subject matter of these spreadsheets through the assertions of privilege, at trial Teva's counsel has elicited testimony from Teva's inhouse counsel about the same subject matter. First, Ms. Julie calculated, on a white board before the jury, Teva's "hypothetical" opportunity as a second Nexium ANDA filer:

Q. So assuming a product, a brand product of approximately \$3 billion annual sales. What is the potential benefit for the first-filer, can you explain how you get there, during the 180-day period?

A. Sure. The first thing you have to do is realize that \$3 billion in annual sales is really \$1.5 billion in 180-day sales, 6 month sales. All right? So you divide it by 2. So you have a \$1.5 billion brand opportunity during the 180 days. Typically oral drugs like this, generics, sell fairly quickly, so you would expect to capture, you know, somewhere around 80, 90 percent of the market certainly by the end of the 6-month period. But if you average it out, say 80 percent during the 6-month period. So if you do 80 percent of those sales --

Q. (Writes.)

A. My math isn't --

Q. I can't do it. I hope you can.

A. 1.5 times 2 is 3, so it's \$1.2 billion dollars, right? But that assumes that you're going to make the sales at the brand price, but you're not, you're going to make them at a generic price and typically a generic price is at least -- is half as much as the brands during that period. So you're looking at probably closer to \$600 million.

Q. (Writes.)

A. Which is a lot of money.

Q. (Writes.) And what would -- now assume that Teva were the second-filer, can you describe how you would calculate the second-filer's opportunity?

A. So if you look at just the next 6 months, so if the second-filer launches on Day 181, right, after the exclusivity is over, you now have two generics that are sharing in that 80 percent of the market, right? The first-filer typically keeps the majority of the share of the market because they've already been selling it. So as a second-filer the most you expect to get is maybe about 40 percent of that market share. So -- but let's just say you get half of it and you split it evenly, because then the math is easier. Then, you know, you're looking at \$300 million. But your price also goes down, so you're probably looking more at like \$200 million, because you have to compete on price in order to get to that share. So really the second-filer is looking at more like \$200 million, assuming it's just a two-generic market.⁶

Second, Ms. Julie testified at length about Teva's sales data and the calculation of net sales, information that she claimed was used during a Prilosec settlement preparation call⁷ (in which she did not participate):

- Q. Did there come a point where Teva provided discovery to AstraZeneca about its sales?
- A. Yes, it did.
- Q. And I think this is in evidence. I'm going to hand the witness what has already been admitted as Exhibit 50, 51 and 57.

* * *

- Q. First, let me find out was this information provided by Teva to AstraZeneca in the Prilosec litigation?
- A. Yes, it was.
- Q. Okay. And how did that come about?
- A. This was in response to discovery requests from AstraZeneca to provide information regarding Teva's sales and profits.

* * *

- Q. But explain to us in brief the type of information that's contained in Exhibit 57?
- A. Okay. So, um, if you look at it, there are various charts in here, um, and you can see information regarding gross sales, you can see all of the deductions that

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⁶ Oct. 31, 2014 Tr., Vol. 1 (Exhibit 4), 64:10-66:6.

⁷ Exhibit 4, 54:15-55:5.

were required under the Impax agreement to get the definition of "net sales" in that agreement, and then you can see what the net sales are and you can also see what the royalties to Impax would be.

Q. Could you just tell us which, um, document -- there should be a three-letter code on the bottom. I just want to use this as an example. If you could just give the three-letter code and page number of what you're talking about, so we can just give an example.

A. You actually have to look at a couple of different ones to get all of it, but if you look say at CAP Page 39.

Q. Okay. Is that what you're looking at?

A. Yes, that is what I'm looking at. You can see that this is information regarding omeprazole. And if we can break this down. It's very small print. But you can see it's broken down by line item based on the different SKU that the product is sold under. You can see that there's a 10 milligram line and then the 20 milligram product is actually sold in three different ways, you know, depending on the quantity of pills.

You then see the units, the gross units, the gross sales numbers. This credit you'd actually have to go to another page, um, to figure out the credit, and I can't line them up sitting here, but there are pages that have all the different things that under the agreement -- I'm looking at maybe Page 41. I'm not sure the numbers line up, but --

Q. Well, can you just explain to us generally what a credit would be?

A. Well, when you're looking at a generic industry, when you sell a product, yes, there's a gross sales number, but there are a lot of things actually the person selling the product never get. They don't get -- because they get rebates they don't get because there are chargebacks under agreements, there are price adjustments that are made. There's a number of things that are deducted to actually get to your true net sales number.

We have an audited way of coming up with what our net sales number is, but that doesn't always match up with what the agreement's way is to get to net sales, because when you contract with -- like we did here with Impax, you'd -- well, everyone had their own definition of what should get deducted. And so it can slightly be different than what we actually produce as audited numbers, which is why we needed to produce reports under the Impax definition of those things that were deducted in order to get to net sales.

So basically net sales is what we actually made on the product.

Q. And can you explain, um, just generally, the other information provided?

A. So after you get to net sales -- right after the credits you get to net units and net sales, and that's the next column, so you deduct the credits from the gross, and then you have your manufacturing costs, so, you know, the cost of the API, the inactive ingredients, all of that kind of thing, and then you get your, um -- okay, you can see there's other things here that are deducted, your selling administrative allowance -- and eventually you get to something called "gross margin," which is the profits. You then take the point that Impax was supposed to get 35 percent of those profits and you can see what money is due to Impax.⁸

Significantly, Ms. Julie testified that this information was used during "a preparation called for discussions with AstraZeneca regarding settlements on Nexium and Prilosec." Ms. Julie's testimony is a waiver of the privilege.

B. Scope of the Waiver

"When . . . disclosure [of privileged information] is made in a federal proceeding or to a federal office or agency and [the disclosure] waives the attorney-client privilege or work-product protection, the waiver extends to an undisclosed communication or information in a federal or state proceeding only if: (1) the waiver is intentional; (2) the disclosed and undisclosed communications or information concern the same subject matter; and (3) they ought in fairness to be considered together." Fed. R. Evid. 502(a). Under this rule, subject matter waiver is appropriate as a matter of fairness where "the privilege holder seeks to use the disclosed material for advantage in the litigation but to invoke the privilege to deny its adversary access to additional materials that could provide an important context for proper understanding of the privileged materials." ¹⁰

⁸ Oct. 31, 2014 Tr. Vol. 1, 45:9-14; 46:6-12; 47:19-50:16.

⁹ Oct. 31, 2014 Tr., Vol. 1, 54:15-55:5.

¹⁰ U.S. Airline Pilots Association v. Pension Benefit Guaranty Corp., 274 F.R.D. 28, 32 (D.D.C. 2011) (citing Charles A. Wright et al., 8 Federal Practice & Procedure § 2016.2 (3d ed., 2010 update); see also Fort James Corp. v. Solo Cup Co., 412 F.3d 1340, 1349 (Fed. Cir. 2005) ("The waiver extends beyond the document initially produced out of concern for fairness, so that a party is prevented from disclosing communications that support its position while simultaneously concealing communications that do not."); see also Texaco Puerto Rico, Inc. v. Dept. of Consumer Affairs, 60 F.3d 867, 883-4 (1st Cir. 1995) ("[A] waiver premised on

"There is no bright line test for determining what constitutes the subject matter of the waiver, rather courts weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosures." ¹¹

There is no question that Teva's waiver was intentional: its counsel has elicited testimony from Teva's in-house counsel in which Ms. Julie provided testimony about the same subject matter that was previously withheld as privileged. Ms. Julie purported to testify about hypothetical market conditions for a second Nexium ANDA filer. Teva is attempting to obtain a tactical advantage by disclosing, at this late date, a single, hypothetical example that Teva apparently believes is favorable to its case, while simultaneously withholding all other spreadsheets containing data regarding Teva's generic Nexium and Prilosec products under the shield of privilege. The Court should therefore hold that Teva has waived the privilege with respect to all spreadsheets containing data described as relevant to generic Nexium launch and the Nexium and/or Prilosec patent litigation settlements.

Fort James Corp. v. Solo Cup Co. involved a patent dispute relating to paper plates. ¹² In the scope of evaluating its production process between 1980 and 1981, Fort James discovered that a particular die used at two of its plants made paper plates that were particularly rigid. ¹³ Fort James subsequently patented the die. ¹⁴ Because plates made using the die were sold while Fort James was studying its commercial production methods, Solo Cup claimed the patent was invalid

inadvertent disclosure will be deemed to encompass 'all other such communications on the same subject.'").

¹¹ Fort James Corp. v. Solo Cup Co., 412 F.3d 1340, 1349 (Fed. Cir. 2005) (citing In re Keeper of the Records XYZ Corp., 348 F.3d 16, 23 (1st Cir. 2003).

¹² 412 F.3d 1340 (Fed. Cir. 2005).

¹³ *Id.* at 1343.

¹⁴ *Id*.

due to the on-sale bar to patentability found in 35 U.S.C. § 102(b). ¹⁵ A patent challenger must meet a two-pronged test to prove invalidity under this section: 1) the product must be the subject of a commercial offer for sale; and 2) the invention must be ready for patenting. ¹⁶

During the course of the litigation, Fort James disclosed to Solo Cup a document containing the privileged statement that "legal counsel has advised a bar was not established during experimental trials at [the two relevant plants]."¹⁷ The district court held this to be a waiver of privilege, but limited the scope of the waiver to documents relating to the first prong of the on-sale bar test (that is, whether there was a commercial offer for sale) and denied Solo Cup's motion to compel disclosure of an "invention disclosure statement discussing invention of pressed paperboard plates to maximize plate rigidity."¹⁸ The Federal Circuit reversed, holding that the scope of the waiver included matters relating to the on-sale bar to patentability generally, rather than just the first prong.¹⁹

Likewise, Teva disclosed a spreadsheet containing hypothetical sales and market data in a tactical effort to disclose limited privileged information (which Teva presumably believes is favorable to its case) while simultaneously withholding all other documents relating to that issue that might provide context for that document. The Court should therefore hold that Teva has

¹⁵ *Id*.

¹⁶ *Id.* at 1350.

¹⁷ *Id.* at 1343.

¹⁸ *Id.* at 1343-44; 1350 ("the court concluded that only communications specifically referencing commercial sales or public disclosures of the invention were within the subject matter of the waiver").

¹⁹ *Id.* at 1350-51 ("The second prong of this test necessarily implicates the conception and reduction to practice or enablement of the invention . . . [a]ccordingly, Fort James's waiver encompassed not only communications involving commercial sales of the claimed invention, but also communications concerning the inventor's recognition and development of the invention.").

waived the privilege with respect to all spreadsheets relating to the generic Nexium launch and the Nexium and/or Prilosec patent litigation settlements.²⁰

CONCLUSION

Defendants' gaming of the discovery process warrants a remedy to avoid unfairness and prejudice to Plaintiffs. Plaintiffs respectfully request that Teva be ordered to immediately produce all 163 King spreadsheets identified on its privilege log so that Ms. King, Ms. Julie, and other witnesses can be examined fully and fairly at trial. Alternatively, Plaintiffs request that the Court strike Ms. Julie's testimony insofar as it pertains to the King spreadsheets, and bar Defendants from calling Ms. Julie or other witnesses on these same subjects.

Dated: November 6, 2014

Thomas M. Sobol, BBO No. 471770 David S. Nalven, BBO No. 547220 Donna M. Evans, BBO No. 554613 Kristen A. Johnson, BBO No. 667261 HAGENS BERMAN SOBOL SHAPIRO LLP 55 Cambridge Parkway, Suite 301 Cambridge, MA 02142 Tel: (617) 482-3700

Fax: (617) 482-3003 tom@hbsslaw.com

²⁰ *Id.*; *see also Airline Pilots*, 274 F.R.D. at 32 (subject matter waiver is appropriate under Fed. R. Evid. 502 as a matter of fairness where "the privilege holder seeks to use the disclosed material for advantage in the litigation but to invoke the privilege to deny its adversary access to additional materials that could provide an important context for proper understanding of the privileged materials."); *Micron Separations, Inc. v. Pall Corp.*, 159 F.R.D. 361, 363 (D. Mass. 1995) (Where alleged patent infringer asserted advice of counsel as defense and produced an opinion letter as to non-infringement, the attorney client privilege was waived as to the "subject matter," which includes "all documents or information which MSI received from any source on the subject matter of whether its product infringed Pall's patent."); *Bear Republic Brewing Co. v. Central City Brewing Co.*, 275 F.R.D. 43, 49-50 (D. Mass. 2011) (waiver of work-product privilege with respect to certain photographs and items obtained by investigator waived the privilege with respect to all other communications regarding that material, "including how it came to be obtained, at whose direction it was obtained, and the manner in which it was obtained").

davidn@hbsslaw.com donnae@hbsslaw.com kristenp@hbsslaw.com

David F. Sorensen

Liaison Counsel and Co-lead Counsel for the Direct Purchaser Class

Daniel Simons
Ellen Noteware
Caitlin G. Coslett
Nicholas Urban
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604
dsorensen@bm.net
dsimons@bm.net
enoteware@bm.net
ccoslett@bm.net
nurban@bm.net

Bruce E. Gerstein
Joseph Opper
Elena Chan
Ephraim R. Gerstein
GARWIN GERSTEIN & FISHER LLP
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com
jopper@garwingerstein.com
echan@garwingerstein.com
egerstein@garwingerstein.com

Co-lead Counsel for the Direct Purchaser Class

Glen DeValerio (BBO #122010) BERMAN DeVALERIO One Liberty Square Boston, MA 02109 Tel: (617) 542-8300

Fax: (617) 542-1194

gdevalerio@bermandevalerio.com

Todd A. Seaver (BBO #645874) BERMAN DeVALERIO One California Street, Suite 900 San Francisco, CA 94111

Tel: (415) 433-3200 Fax: (415) 433-6382

tseaver@bermandevalerio.com

Liaison Counsel for the End-Payor Class

Steve D. Shadowen HILLIARD & SHADOWEN LLC 39 West Main Street Mechanicsburg, PA 17055 Tel: (855) 344-3298 steve@hilliardshadowenlaw.com

Anne Fornecker
Daniel Gonzales
HILLIARD & SHADOWEN LLC
919 Congress Ave., Suite 1325
Austin, TX 78701
Tel: (512) 851-8990
anne@hilliardshadowenlaw.com
daniel@hilliardshadowenlaw.com

Kenneth A. Wexler
Bethany R. Turke
Justin N. Boley
WEXLER WALLACE LLP
55 W. Monroe Street, Suite 3300
Chicago, IL 60603
Tel: (312) 346-2222
Fax: (312) 346-0022
kaw@wexlerwallace.com
brt@wexlerwallace.com
jnb@wexlerwallace.com

J. Douglas Richards
George Farah
Sharon K. Robertson
Hiba Hafiz
COHEN MILSTEIN SELLERS & TOLL, PLLC
88 Pine Street, 14th Floor
New York, New York 10005
Tel: (212) 838-7797

Fax: (212) 838-7745

drichards@cohenmilstein.com srobertson@cohenmilstein.com

Jayne A. Goldstein POMERANTZ LLP 1792 Bell Tower Lane Suite 203

Weston, FL 33326 Tel: 954-315-3454 Fax: 954-315-3455

jagoldstein@pomlaw.com

Co-Lead Counsel for the End-Payor Class

Scott E. Perwin Lauren C. Ravkind Anna T. Neill KENNY NACHWALTER P.A. 1100 Miami Center 201 South Biscayne Boulevard Miami, FL 33131 Tel: 305-373-1000 Fax: 305-372-1861

Counsel for Walgreen Plaintiffs

Barry L. Refsin HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER One Logan Square, 27th Floor Philadelphia, PA. 19103 Tel: 215-568-6200

Monica L. Rebuck
HANGLEY ARONCHICK SEGAL PUDLIN &
SCHILLER
4400 Deer Path Road, Suite 200
Harrisburg, PA 17110
Tel.: 717-364-1007

Counsel for Rite Aid Plaintiffs

Bernard D. Marcus Moira Cain-Mannix Brian C. Hill Erin Gibson Allen MARCUS & SHAPIRA LLP One Oxford Centre, 35th Floor Pittsburgh, PA 15219 Tel.: 412-338-3344

Counsel for Giant Eagle, Inc.